Remarks

General

Applicants herewith provide amended Specification paragraph [0036], as required by the Office Action that removes allegedly new matter.

Applicants also provide with replacement drawing sheets that meet the requirements for size, and spacing under 37 CFR 1.84.

No new matter is added by these amendments to the Specification and to the Drawings. Therefore, Applicants submit that entry of the amendments is appropriate.

Claims

Claims 1-15 and 32-68 are pending in the application.

Claims 2, 4, 7, 10-14, 32-54, 56-58, 60-61, 63, 66-70, 72-75, 77 and 79-82 are withdrawn from consideration.

Applicants herewith amend no claims, delete no claims, or add no new claims.

Therefore, Claims 1, 3, 5, 6, 8, 9, 15, 55, 59, 62, 64, 71, 76 and 78 are currently pending in the application.

The Office Action has indicated that the rejections not repeated therein have been withdrawn. Thus Applicants note that rejection of claims 1, 3, 5, 6, 8, 9, 15, 55, 59, 62, 64, 65, 76, and 78 under 35 U.S.C. § 102(b) or, in the alternate under 35 U.S.C. § 103(a) by U.S. Application Publication No. 2001/0007747 A1 is withdrawn. Applicants thank the Examiner.

Rejections under 35 U.S.C. § 112, First Paragraph and under 35 U.S.C. § 101

The Office Actions has rejected claims 1, 3, 5, 6, 8, 9, 15, 55, 59, 62, 64, 71, 76 and 78 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. The Office Actions has also rejected claims 1, 3, 5, 6, 8, 9, 15, 55, 59, 62, 64, 71, 76 and 78 under 35 U.S.C. § 112, first paragraph, for allegedly lacking substantial or credible utility. Applicants respectfully traverse the rejections.

The Office Action avers that giving the broadest claim scope, the claims do not describe the invention in such a way that a skilled person would believe that the Applicants had the possession of the invention. In support of this contention and also in support of the contention that claimed invention lacks utility, the Office Action states "Utility of the claimed composition, kit and reaction mixture resides in the product produced, *i.e.*, cDNA. Not all mRNA, or cDNA have utility. Utility of the claimed composition/kit/reaction mixture is deemed to be a lynchpin to patentability. Accordingly, the claims have not been construed as requiring the "template" be any nucleic acid that has a specific, substantial, and credible utility or a well-established utility. Applicants respectfully traverse the rejection and address them together.

The invention and claims are related to compositions and kits comprising 2 or more different, modified, monomeric deoxyribonucleotide triphosphates, wherein said modified deoxyribonucleotide triphosphates have the ability to bind one or more detectable labels. The compositions and kits are directed to modified dNTPs and not to any mRNA, or DNA. Thus, Applicants submit that claims are not failing to meet the requirements of 35 U.S.C. § 112, first paragraph.

Again, the Applicants invention is directed to modified, monomeric dNTPs and not to any cDNA or mRNA. However, the Office is incorrect in presuming that "Not all mRNA, or cDNA derived therefrom, has utility". The Office is perhaps, confusing the utility (or lack thereof) of isolated, partially sequenced, expressed sequence tags (ESTs) that were found to be lacking substantial utility (see In re Fisher, 421 F.3d 1365 (Fed. Cir. 2005)), with mRNAs that are expressed by various eukaryotic or prokaryotic cells. If a cell is expressing an mRNA (for example, for erythropoietin, or for a receptor), that mRNA when isolated by an inventor, has utility or it would not have been transcribed it from its DNA (cell's genetic material). Applicants submit that a utility of a naturally-occurring full-length nucleotide sequence when isolated in its entire length, is well-established. Thus, Applicants submit that claims do not lack substantial, credible, or well-established utility and respectfully request that the rejection should be withdrawn.

Rejections under 35 U.S.C. § 112, Second Paragraph

The Office Action has rejected claims 1, 55, and 76 for allegedly being indefinite for use of the term "modified". The Office Action avers that the term "modified" is not defined by the claim, and that specification does not provide standard for ascertaining the requisite degree....The Office Action has also similarly rejected claims for use of the term "different" and "detectable". Applicants respectfully traverse the rejection.

The Specification at paragraph [0026] defines the term "modified" (reproduced below for ease of discussion)

> **[0026]** **Modified Nucleotide**. As used herein "modified nucleotide" refers to any molecule (preferably a chemical compound) that can be incorporated in a nucleic acid molecule during nucleic acid synthesis or any (i) molecule that can otherwise function as a nucleotide in a nucleic acid molecule or sequence and (ii) has the ability to bind (covalently, non-covalently, directly or indirectly) with or to one or more labels, preferably through one or more reactive groups located on the modified nucleotides. A modified nucleotide can be any nucleotide having one or more modifications, including any type of modification in any location or number of locations within the nucleotide. Such modification or modifications may be included in the base, sugar or phosphate structures (or combinations thereof) and a modification can change the characteristics or structure or function of one or a number of elements of the nucleotide. Modifications can include addition of one or more molecules or chemical groups, substitution of one or more molecules or chemical groups with other molecules or chemical group, and/or deletion of one or more molecules or chemical groups or conjugate. Preferably, a modified nucleotide does not contain a detectable label or are unlabeled, and are preferably not bound or conjugated or complexed to a detectable label prior to incorporation of the modified nucleotide in a nucleic acid molecule. In any event, the modified nucleotide can be labeled (or bound or complexed with or to one or more labels) prior to or after such modified nucleotide are incorporated into a nucleic acid molecule. In one aspect, a modified nucleotide does not contain or lacks (or is not interacted with or not bound to) a fluorophore and/or a

fluorescent dye and/or a fluorescent moiety, although such molecules may be added once the modified nucleotide is incorporated in a nucleic acid molecule. In another aspect, a modified nucleotide has not been interacted with a fluorophore and/or a fluorescent dye and/or a fluorescent moiety prior to incorporation of the modified nucleotide into a nucleic acid molecule. In other aspects, a modified nucleotide is not complexed or attached to other specified labels, bioluminescent labels and enzyme labels or combinations thereof. The modified nucleotides include, but are not limited to, nucleotides containing one or more reactive groups such as primary amine, hydroxyl , sulfhydryl, aldehyde, or carboxylate Group. Examples of modified nucleotides of the invention include for example, aminoallyl-dUTP (AA-dUTP), aminohexyl-dATP (AH-dATP), aminoallyl-dCTP (AA-dCTP), as well as those disclosed in Folsom *et al., Anal. Biochem. 82*(2):309-314 (Nov. 1, 1989); GebeyeHu *et al., Nuc. Acid Res. 15*(11):4513-4534 (1987); ZoFall *et al., Nucl. Acid Res. 28*(21):4382-4390 (2000).

Similarly, the term "detectable labels" is defined at paragraph [0031] (reproduced below).

[0031] **Detectable Labels**. A "detectable label" or "detectably labeled" or "label" or "labeled" as used herein refers to any molecule or moiety or composition or complex which can be determined to be present in a sample of interest or otherwise detected by one or a number of means of detection well known in the art. Such detection may be accomplished by visualization, fluorescence spectrometers, absorption spectrometers, fluorescence microscopes, transmission light microscopes, flow cytometers. Fiber optic sensors, and immunoassay instruments. Chemical analysis methods can include infrared spectrometry, NMR spectrometry, absorption spectrometry, fluorescence spectrometry, mass spectrometry and chromatographic methods. Such labels may be complexed with or linked or bound to any compound or element to allow detection of the labeled compound or element. Detectable labels include, but are not limited to, fluorescent labels (including fluorophores), radioactive isotopes, chemilurminescent labels, bioluminescent labels, and enzyme labels.

As for the term "different", it has the same meaning as in any dictionary. The term "different" is not used in conjunction with a particular skill. The term "different" has the dictionary meaning of being dissimilar, not being the same. In view of the foregoing, Applicants submit that claims are not indefinite and respectfully request that the rejections should be withdrawn.

Conclusion

Applicants have made an earnest effort to place their application in proper form for examination and allowance. In view of the foregoing, Applicants respectfully request reconsideration of this application.

Respectfully Submitted,

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